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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/886,349	06/20/2001	Yasir Skeiky	014058-009070US	4456

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EXAMINER

SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 02/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/886,349

**Applicant(s)**

SKEIKY ET AL.

**Examiner**

Rodney P. Swartz, Ph.D.

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-19, 70, 72-75, 83 and 85-88 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 70, 72-75 and 88 is/are allowed.
- 6) ☒ Claim(s) 1, 4, 5, 19, 83 and 85-87 is/are rejected.
- 7) ☒ Claim(s) 2, 3 and 7-18 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) ✓           |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>10-7-04</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Applicants' Response to Office Action, received 26 November 2004, is acknowledged. Claims 1, 70, 72, and 83 have been amended. Claims 6, 20-69, 71, 76-82, and 84 have been cancelled.
2. Claims 1-5, 7-19, 70-75, 83, and 85-88 are pending and under consideration.

### **Rejections Withdrawn\Moot**

3. The provisional rejection of claim 6 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 62-64 of copending Application No. 09/597,796 is moot in light of the cancellation of the claim.
4. The rejection of claim 84 under 35 U.S.C. 112, second paragraph, indefiniteness, for polypeptides which have substitutions in "the active site triad" is moot in light of the cancellation of the claim.
5. The rejection of claims 7 and 88 under 35 U.S.C. 112, second paragraph, as being indefiniteness, is withdrawn in light of applicants clarification.

Applicants clarify that claim 7 is drawn to a composition comprising a fusion polypeptide having the amino acid sequence of SEQ ID NO:18, whereas claim 88 is drawn to a fusion polypeptide comprising the amino acid sequence of SEQ ID NO:18.

The examiner has considered applicants' clarification.

6. The rejection of claims 2 and 3 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,627,198 is withdrawn.

Applicants argue that newly amended claim 1 recites a limitation that the Pat. No. 6,627,198 does not have nor suggest. Therefore, claim 1 and its dependent claims are not obvious over claim 1 of Pat. No. 6,627,198.

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The examiner has considered applicants' argument, and finds it persuasive in light of the amendment of claim 1 wherein the embodiment of dependent claim 2 is a composition comprising SEQ ID NO:12 or 14 or fragment, and a polypeptide comprising at least 195 amino acids from the N-terminus of SEQ ID NO:2 or 4. The recitation of "a polypeptide comprising at least 195 amino acids from the N-terminus of SEQ ID NO:2 or 4 encompasses the amino acid substitution restriction of claim 1.

The examiner has considered applicants' argument, and finds it persuasive in light of the amendment of claim 1 wherein the embodiment of dependent claim 3 is a composition comprising SEQ ID NO:12 or 14 or fragment, and a polypeptide comprising at least 195 amino acids from the N-terminus of SEQ ID NO:2 or 4 and further comprising a polypeptide comprising at least about 132 amino acids from the C-terminus of SEQ ID NO:2 or 4. The recitation of "a polypeptide comprising at least 195 amino acids from the N-terminus of SEQ ID NO:2 or 4 encompasses the amino acid substitution restriction of claim 1 and further comprising a polypeptide comprising at least about 132 amino acids from the C-terminus of SEQ ID NO:2 or 4 encompasses the amino acid substitution restriction of claim 1.

7. The provisional rejection of claims 1-5 and 19 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/359,460 is withdrawn in light of the cancellation of claim 1 of copending Appl. No. 10/359,460.

8. The provisional rejection of claims 1-4, 8, 17, and 19 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 62-64 of copending Application No. 09/597,796 is withdrawn in light of the cancellation of claim 6, amendment of claim 1 and applicants' arguments.

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9. The rejection of claims 70-75, 83, and 85-87 under 35 U.S.C. 112, second paragraph, indefiniteness, for polypeptides which have substitutions in "the active site triad" is withdrawn in light of the amendment of the claims.

Applicants argue that amendment of claims 70 and 83 obviate the rejection.

The examiner has considered applicants' argument, and finds it persuasive.

10. The rejection of claims 9-16 and 18 under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn.

### **Rejections Maintained**

11. The rejection of claims 1, 4, 5, and 19 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,627,198 is maintained for reasons of record.

Applicants argue that newly amended claim 1 recites a limitation that the Pat. No. 6,627,198 does not have nor suggest. Therefore, claim 1 and its dependent claims are not obvious over claim 1 of Pat. No. 6,627,198.

The examiner has considered applicants' argument, but does not find it persuasive for the reasons put forth in the original rejection. One embodiment of claim 1 is a composition comprising any immunogenic fragment of SEQ ID NO:12 or 14 and any immunogenic fragment of SEQ ID NO:2 or 4 and thus, does not require that it contain any of the recited substitutions. Thus, one of the embodiments under this scope of the claims is SEQ ID NO:20. Since dependent claim 5 recites that the fusion has the amino acid sequence of SEQ ID NO:20 and claim 1 of Pat. No. 6,627,198 recites a polypeptide comprising the identical sequence, i.e., SEQ ID NO:26, claim 5 does read on claim 1 of U.S. Pat. No. 6,627,198. Likewise, claims 4 and 19

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also comprise SEQ ID NO:20 as one of their embodiments and therefore, also read on claim 1 of U.S. Pat. No. 6,627,198.

### **Claim Objections**

12. Claims 2, 3, and 7-18 are objected to due to dependence from rejected claims.

### **Claim Rejections - 35 USC § 112**

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 83 and 85-87 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 83 recites "An isolated polypeptide encoding a fusion polypeptide". It is unclear how one polypeptide encodes another polypeptide. Claims 85-87 depend from claim 83, but do not clarify the indefiniteness.

### **Conclusion**

15. Claims 1, 4, 5, 19, 83 and 85-87 are rejected. Claims 2, 3, and 7-18 are objected to for improper dependency. Claims 88, 70, and 72-75 appear to be allowable.


16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

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The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
RODNEY P. SWARTZ, PH.D.  
PRIMARY EXAMINER  
Art Unit 1645

February 14, 2005